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Transmitted herewith for filing under 35 U.S.C. 111 and 37 C.F.R. 1.53 is the patent application of:

Magnus BOLMSJO

For: **METHOD AND DEVICE FOR COMBINED HEAT TREATMENT OF BODY TISSUE**

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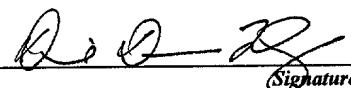
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Dated: **August 23, 1999**


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METHOD AND DEVICE FOR COMBINED HEAT TREATMENT OF BODY TISSUE

TECHNICAL FIELD OF THE INVENTION

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The invention concerns a method and device for heat treatment of bodily tissue according to patent claims 1 and 12, respectively.

Heat treatment yields good treatment results with certain types of disease conditions involving unnatural growth of tissue. The tissue is heated to the extent that it dies. Examples of such disease conditions are certain types of cancer and benign prostate hyperplasy, BPH. During treatment certain portions of the tissue are heated so that tissue death ensues, while other portions of tissue must or should be protected. The disease conditions which are primarily indicated are those which occur in tissue surrounding cavities in the body.

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Corresponding disease conditions can also occur in animals, where corresponding treatment can be brought to bear. Above all, treatment of the prostate in domestic animals, such as dogs, can be topical.

20

STATE OF THE ART

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Different devices can be used in order to induce heating. Devices for heating by means of laser as well as with microwaves and radio frequencies are common. A technique is known through US-A-5, 257,977, according to which a catheter is provided with a reservoir for fluid. The reservoir is flexible and is connected via channels through the catheter with a heating device located outside the body. A fluid is heated in a heating device and circulated through the channels and the reservoir that to some degree expands for better contact with the tissue. The rise of temperature in the reservoir also brings about heating of the surrounding tissue. Treatment is affected by controlling the temperature of the circulating fluid.

Since the channels pass through tissue that should not be treated, they must be heat insulated. According to US-A-5, 257,977 the heat insulation is brought about by means of a space filled with gas that surrounds the channels. The function of the heat insulation is very important, for which reason great care and considerable expense must be devoted to this part of the treatment catheter. Another disadvantage with the device according to US-A-5, 257,977 is that desired control of the temperature is difficult to achieve for the reason that the distance between the heating device and the area of treatment is relatively large and because the temperature of the circulating fluid should not exceed 140 °F (60 °C) in order to avoid an effect on the urethra outside of the prostate and penis brought about by heat in the in/out channels.

A more highly developed catheter for treatment is shown and described in WO 97/02794, according to which a heating device is contained inside an expandable reservoir. The heating device is provided with energy from an assembly outside of the body for heating of fluid inside the reservoir. Some of the disadvantages involving undesirable heating of certain tissue are avoided in this manner. The heating device is designed according to WO 97/02794 as a resistance wire or similar and heats the fluid through convection. The heat transferred from the fluid to the surrounding tissue gives locally good results. A disadvantage is that the effect in the tissue at a farther distance from the reservoir is insignificant, for which reason the volume of tissue that can be treated is limited with this technique.

Heat treating with a treatment catheter that is equipped with a microwave antenna is also known with the mentioned course of disease. Examples of such microwave treatment are known previously through US-A-5480417 and US-A-5234004. Characteristic for previously known microwave treatment is that the prostate tissue is heated with microwaves. The intention is to heat parts of the prostate gland. The element that emits the microwave radiation consists of a coaxial cable that is included in a catheter for treatment. Cooling fluid circulates through the catheter. The intention with the cooling is to protect the prostatic urethra, that is to say the

part of the urethra that runs through the prostate gland from being affected and damaged by the heat that is generated by the microwaves. Another reason for cooling the catheter is to transport away waste heat in the coaxial cable.

5 In several of these previously known techniques cited earlier the goal of the treatment was not made explicit but it was rather merely indicated that the invention should be used for heat treatment of the prostate. Different levels of heat treatments occur in the literature. So-called hyperthermy treatments have in general the goal only to increase the temperature
10 moderately, < 113 °F; 45 °C. It is known that histological changes in tissue do not occur with temperatures less than 113 °F (45 °C) and that the temperature must exceed 122 °F (50 °C) in order to achieve destruction of tissue in a short time, on the order of one hour or less. In connection with the described invention heat treatment is meant to have such a high temperature
15 that the tissue coagulates, i.e., dies.

It has long been viewed as important to protect the prostatic urethra during microwave treatment of benign prostate enlargement. This protection of the prostatic urethra hinders the treatment from being really effective, however, since parts of the obstructing tissue closest to the urethra are not
20 heated sufficiently in order to coagulate because of the cooling. Neither are there any medicinal-scientific attestations that non-destruction of the prostatic urethra should be preferred. To the contrary it can be argued that destruction of the prostatic urethra along with other tissue means that necroticized tissue is not encapsulated but is naturally discharged with urine
25 during the healing process. The clinical result of heat treatment of the kind envisioned here is dependent on the amount of tissue that coagulates. The degree of coagulation depends in turn on temperature in combination with the length of treatment. The temperature in turn depends on the input of energy and the carrying away of heat by the blood flow. Since different parts
30 of the prostate can have different degrees of blood flow, there is a risk that certain areas will not achieve therapeutic temperature when microwaves are used for heating.

There are also designs with uncooled catheters for treatment. In these the microwave power has been so low that the tissue temperature has not been sufficient to achieve coagulation. Because of cable losses the development of heat in the feed cable (coaxial cable) itself that transmits microwaves through the urethra to the prostate is so high that uncooled catheters can be used only with low microwave power, for example 20 watts. This magnitude is insufficient to bring about tissue necrosis in the prostate and produces only an insignificant heating of the tissue. Equipment of this kind also yields generally poor objective treatment results.

THE INVENTION IN SUMMARY

A purpose of the invention is to increase the effectiveness of treatment with a treatment catheter of previously known technology at the same time as to diminish the risk of maltreatment of tissue. The diminution of risk depends among other things on decreasing the amount of microwave power applied in comparison with known technology. The duration of treatment can also be shortened many times with the invention shown in comparison with known technology. According to preferred embodiments it will also be possible partly to treat tissue far from the prostatic urethra and partly to secure destruction of the prostatic urethra itself and the surrounding area in a controlled way. This purpose is achieved by incorporation of the special features described in patent claims 1 and 12, respectively.

The effectiveness of treatment is increased in that a device for treatment according to the invention comprises means developed to expand the treatment catheter in the longitudinal direction from the apex of the prostate or beyond all the way up to and including the base of the bladder. The cavity that is constituted by the prostatic urethra is filled by a bolus or reservoir filled with fluid so that a good fit occurs between the treatment catheter and the tissue. Separate devices for treating the tissue around the prostatic urethra and more distant tissue are included. Through this means it

is possible to control the supply of power in a better way, which increases safety for the patient and diminishes the risk of damage caused by the treatment as a result of high total power output.

Further advantages and special features of the invention emerge from the following description, drawings, and dependent patent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in more detail with the aid of examples of embodiments with reference to the attached drawings on which:

FIG 1 is a principal cross-sectional view in the longitudinal direction of an embodiment of a treatment catheter according to the invention.

FIG 2 is a transverse sectional view from line *II-II* in FIG 1 and

FIG 3 is a transverse cut through the prostate along line *III-III* in FIG 1 and a treatment catheter inserted into it.

FIG 4 is a principal cross-sectional view in the longitudinal direction of an alternate embodiment of a treatment catheter according to the invention.

FIG 5 is a principal block diagram that shows how a treatment catheter can be included in a treatment assembly,

FIG 6 shows a primary principal embodiment of a combined heating device included in the invention.

FIG 7 shows another principal embodiment of two heating devices included in the invention and

FIG 8 is a principal block diagram that shows how energy can be supplied to two heating devices included in the invention.

THE INVENTION

In the embodiment of a treatment catheter according to the invention shown in FIG 1 a fluid reservoir 11 is arranged externally on a treatment

catheter 12. The treatment catheter is intended primarily for treatment of prostate tissue. Fluid reservoir 11 is elastic and in FIG 1 is expanded by introduction of fluid 13 into it. When fluid is introduced into reservoir 11, it expands and fills the cavity constituted by the prostatic urethra. Contact
 5 between reservoir 11 and the prostate tissue is good.

Treatment catheter 12 according to FIG 1 is introduced through the urethra so that tip 16 extends into urinary bladder 21. A bladder or balloon 18 connected with the treatment catheter is expanded inside urinary bladder 21 and prevents unintended withdrawal of the treatment catheter during the
 10 process of treatment. The active part of the treatment catheter is thus centrally located in the tissue that is to be treated, in this case in prostate 19. The treatment catheter 12 is flexible and pliable in order to be introduced flexibly through the urethra to the treatment position.

Urinary bladder 21 is connected via bladder neck 21' into the urethra.
 15 As can be seen in FIG 1, the bladder neck 21' is expanded along with the upper part of the prostatic urethra when fluid reservoir 11 is expanded, whereby good contact with the tissue is maintained. This is favorable for many reasons. Bladder neck 21' and the surrounding tissue can often have a different flow-through of blood than other parts of the prostate. The blood
 20 flow-through leads to heat being conducted away from the treatment area so that the resulting temperature of the tissue is different in the opening to the urethra in comparison with central parts of the prostate.

A first heating device 10 is arranged inside treatment catheter 12 for heating of the surrounding tissue. First heating device 10 emits
 25 electromagnetic radiation, preferably in the form of microwaves. First heating device 10 preferably comprises a microwave antenna. Energy emitted from first heating device 10 is absorbed to a smaller part by the fluid, which in a common embodiment consists of water or a solution of cooking salt, and to a larger part energy radiates out and is absorbed in the surrounding tissue.
 30 Energy is supplied via feed cable 15 from energy supply unit 41 (see FIG 6). The electromagnetic radiation emits energy to the surrounding tissue up to a

certain distance from the urethra. In a preferred embodiment first heating device 10 comprises a coil antenna.

In FIG 1, reservoir 11 is expanded to its working volume by fluid 13 that has been conducted into it. Reservoir 11 is then the shape of a cigar with its greater length in the longitudinal direction of the treatment catheter. Reservoir 11 is arranged on the outside of the treatment catheter and in one embodiment can have a somewhat larger part of reservoir 11 on the underside of the treatment catheter. With expansion of reservoir 11 the treatment catheter is lifted upwards. Fluid 13 is conducted through channel 22 that is designed as a tube that extends through treatment catheter 12 (see also FIG 2). During treatment a second heating device 29 heats the liquid in reservoir 11. The expansion of reservoir 11 leads to very good contact against the prostatic urethra.

By carrying out heat treatment of the prostate tissue with two independent energy sources it is possible effectively to treat different parts of the prostate. With the invention it is thus for the first time possible to treat with heat in an effective and simultaneous manner i) the base of the bladder, ii) the prostatic urethra and adjacent area along with iii) parts in the prostate located farther away.

Feed cable 15, through which first heating device 10 is supplied with energy, becomes hot as a result of cable losses. Losses in the feed cable are typically around 1 dB per meter at the microwave frequencies that are commonly employed (500 – 2500 MHz). In order to avoid thermally induced injury to tissue because of these cable losses outside the area of treatment, for example on the sphincter muscle that surrounds the urethra outside the prostate, feed cable 15 is cooled. This is accomplished by cooling channels 27 that are included in treatment catheter 12 (see also FIG 4), preferably around feed cable 15. In an embodiment according to the invention cooling channels 27 have a delimitation wall 28, at which cooling fluid circulating in cooling channels 27 returns. In this way cooling of heating device 10, reservoir 11, and the prostatic urethra with its mucous membrane is

prevented. This means in turn that the power that has to be supplied from unit 14 can be decreased in comparison with techniques that use cooled treatment catheters and where cooling is done along the prostatic urethra. With lower power levels the risk of malpractice is lessened along with injury to healthy tissue outside the prostate.

In the treatment catheter fluid channel 26 that ends in balloon 18 is also present. Through it fluid can be supplied for expansion of balloon 18 when the treatment catheter is brought into the desired position for treatment. Fluid channel 26 is also used in order to empty balloon 18 after treatment is completed and before the treatment catheter is withdrawn from the urethra. A conventional hypodermic needle or similar is suitably used for the filling and emptying of balloon 18.

The heating of bladder neck 21' and an adjacent part of prostatic urethra 40 that can be brought about by first heating device 10 is in many cases insufficient, especially in the area near bladder 21. In order to increase the possibility of heating in this area a second heating device 29 is therefore arranged in treatment catheter 12 inside fluid reservoir 11. Second heating device 29 comprises in one embodiment a resistance wire or similar with good heat transfer through treatment catheter 12 and the liquid in fluid reservoir 11.

In the embodiment shown in FIG 1, the coil antenna also embodies second heating device 29 in that the coil antenna is embodied with both inductance L, a certain capacitance, and, with suitable direct current resistance R. See also FIG 6. The coil antenna is supplied both with microwave energy and direct current (or low frequency alternating current) and thus functions both as a microwave-emitting unit and as a resistive heating element. According to one embodiment direct current is supplied in parallel simultaneously with microwave energy from energy supply unit 14. In an alternate embodiment direct current and microwaves are supplied alternately via a coaxial relay or similar electronic component that alternately transmits microwaves and direct current, respectively, in feed cable 15.

Fluid 13 in the reservoir is heated by second heating device 29 to such a temperature that adjacent tissue is heated for example to 140 °F (60 °C) and coagulates. At this temperature the duration of treatment is about 1 hour. Depending on the size of the area to be treated and the chosen
 5 temperature of treatment the duration of treatment can be chosen to be both shorter and longer. By raising the treatment temperature in fluid reservoir 11 via second heating device 29 to a range of 194 °F- 302 °F (90 °C- 150 °C) the duration of treatment can be decreased to an order of some minutes, for example 5 - 20 minutes. At these high temperatures the tissue hardens and
 10 forms a shell and can at least for a transitional time function as a so-called stent.

Since the highest temperature is reached in the tissue closest to reservoir 11, the prostatic urethra, and the mucous membrane in the urethra, i.e. the part of the urethra that passes through the prostate in the area of
 15 treatment, will to a high degree be affected and thus destroyed. This part of the urethra reforms relatively quickly, however. Temperature sensors 23, 23', and 23'' are arranged on carrier 24 in order to be able to track the temperature development during heat treatment. Carrier 24 can be extended through a channel or tube 25, which runs through the treatment catheter.
 20 Carrier 24 or temperature sensor 23 is suitably embodied with, or as, a tip that can penetrate in part a membrane or wall in the treatment catheter and in part the bodily tissue. Tube 25 is embodied so that carrier 24 with temperature sensors 23 is extended out of the treatment catheter at a suitable angle and can be driven out to a suitably radial distance from the
 25 treatment catheter. It is also possible to array several carriers for the different temperature sensors 23.

A second temperature sensor 37 can also be arranged in treatment catheter 12 in or, as in the embodiment shown, inside reservoir 11 and preferably in heat-conducting contact with reservoir 11.

30 Heating of tissue also occurs partly at a short distance by heating of the fluid contained in the reservoir, which emits heat directly via heat conduction to adjacent tissue, and partly at a longer distance by

electromagnetic radiation. The total area of treatment is larger than with conventional heating, which means that larger portions of tissue can be reached and that treatment can be adjusted better for every patient and for conditions relevant to the patient than was the case with previously known technology.

A resultant heat profile, i.e. a curve which indicates the temperature of tissue radially outwards from the center of the treatment catheter, is more elongated than when only microwave or direct heat is used. It thus becomes possible to treat a larger volume. Through the fact that power from different energy sources controls both heating elements it is possibly precisely to control the appearance of the heat profile. In large prostate glands it can, for example, be advantageous to use a relatively high degree of microwave energy with a longer range, while small prostate glands can be treated with the second directly heating element with a shorter range.

First heating device 10 and second heating device 29 are preferably arranged so that the heating power can be controlled independently of each means of heating. A larger prostate is suitably treated with high power in the two heating device 10 and 29, while a smaller prostate is treated primarily or entirely with the second heating device 29. The latter course is also followed if it has been confirmed that the change in the tissue occasioned by disease is concentrated at the bladder neck and adjacent prostate tissue.

The bladder neck is most often a problem when heat treating BPH, because the bladder neck often has a high degree of blood flow and thus a high transfer away of heat. The result is that the temperature often does not become sufficiently high to bring about a coagulation of tissue merely with microwaves. This problem is avoided with the invention as now designed in that the bladder neck is instead mainly heated directly by second heating device 29 and the liquid in fluid reservoir 11. The liquid, which is in good thermal contact with the bladder neck, has such a high temperature (> 140 °F; 60 °C) that the outer parts of the bladder neck are coagulated because of heat transfer. If the temperature in fluid reservoir 11 is sufficiently

high, the blood flow in the bladder neck no longer matters, since the coagulation of the tissue happens very quickly.

When treatment has ended, the supply of energy to heating device 10 and 29 is interrupted and reservoir 11 is allowed to return to normal body temperature. It is unsuitable to remove the treatment catheter as long as the reservoir has a temperature that can cause injury when the reservoir is passed through the body. For this reason the temperature in reservoir 11 is registered constantly, so that removal of the treatment catheter can occur as soon as the desired temperature has been reached.

When catheter 12 is introduced into the urethra with a tip in urinary bladder 21, drainage of urine and perhaps other liquid from the urinary bladder can occur through a drainage channel incorporated in catheter 12. The drainage channel runs through the whole length of catheter 12 and ends with an opening 20 near the tip of catheter 12. With certain types of treatment it can be suitable to leave catheter 12 for some time after treatment. Even during this time the function of the drainage channel is to drain the urinary bladder.

As soon as urine again passes through the urethra in the prostate, the treated and dead tissue will be able to flush with the urine. A remaining cavity in the prostate caused by removed tissue assures the passage of urine in the correct manner. The cavity initially has a form that corresponds with the form of reservoir 11 during the time of treatment, i.e. with the largest cross-area closest to urinary bladder 21. The healing process including the rejection of coagulated tissue can continue for a time of some months.

As a complement to, or part of, the heat treatment according to the above, some form of medicine can be introduced into fluid reservoir 11. Fluid reservoir 11 is modified in that case so that it allows passage of the medicine. Fluid reservoir 11 is suitably embodied so that the medicine can diffuse through the wall of fluid reservoir 11, but it is also possible to incorporate permeable channels or similar in the wall. According to one treatment, medicine against pain can be included in the fluid. Other medicines can also be used for direct treatment.

FIG 2 schematically shows an embodiment of a treatment catheter 12.

Treatment catheter 12 is designed with a number of cavities and channels extending along the treatment catheter. Feed cable 15 runs through a central cavity 30, which is preferably well shielded. Cooling fluid is transported in separated cooling channels 27, preferably in a circulating system. In a first cooling channel 27 a tube 25 for carrier 24 is arranged. In a similar manner fluid channel 26 for balloon 18 and channel 22 for fluid reservoir 11 are arranged in other channels 27. A drainage channel, which ends in opening 20 in the treatment catheter, can be arranged in a similar way in a cooling channel.

In FIG 3 is shown schematically in cross section how the propagation of heat primarily from second heating device 29 extends through prostate 19 with an ever lower intensity. Intensity I_1 is closest to fluid reservoir 11. The intensity drops off quickly to level I_2 and sinks to level I_3 at a farther distance from fluid reservoir 11. In the area closest to fluid reservoir 11 the temperature of the tissue can be raised to a very high level as a result of the high intensity level I_1 so that the tissue hardens into a shell, especially as adjacent prostate tissue is compressed to a certain degree. The compressed prostate tissue also leads to a lessened need for power, since less heat is transferred by blood flow.

In the embodiment according to FIG 4, fluid reservoir 11 has a shorter extension in the longitudinal direction of the treatment catheter and assumes its active position completely within the upper part of the urethra closest to bladder neck 21'. This design is especially usable when the area that should be primarily treated lies around the bladder neck. First heating device 10 is suitably activated so that treatment with microwave-induced heat is concentrated in the area around the central prostate. The second heating means assures that the area closest to the balloon and especially bladder neck 21' receives effective treatment. Second heating device 29 according to this embodiment makes possible higher treatment temperatures and a more

limited volume. As can be seen in FIG 4 the radial range for heat propagation is greater for the radiating microwave component than for the directly applied component from reservoir 11, where heat is transported out of the tissue through heat conduction. Intensity levels I'_1 , I'_2 , I'_3 which are produced by first heating device 10 are located at a farther distance from treatment catheter 12 than corresponding intensity levels from second heating device 29.

In the embodiment shown in FIG 4, first heating means 10 consists of a coil antenna with low or negligible resistive power loss. Second heating means 29 includes instead a resistive heating element, for example, in the form of a resistance wire or a resistor (see also FIG 7).

The block diagram in FIG 5 schematically shows the various function blocks that can be included in a treatment assembly with a treatment catheter according to the invention. As indicated above, energy is supplied to heating device 10 from energy supply unit 14. A central control unit 32 is operatively connected with energy supply unit 14 and a display unit 33 and with a pumping and cooling device 34 and a fluid supply device 35. Control unit 32 is additionally operatively connected with an input device, for example, in form of a keyboard 36. Control unit 32, keyboard 36, and display unit 33 can also be included in a conventional computer with a monitor and keyboard.

Control unit 32 is operatively connected with temperature sensors 23 and 37 and can control energy supply unit 14 dependent on the current temperature in the area of treatment so that suitable power is supplied to heating device 10. In this manner it is possible to increase the temperature considerably with good safety in fluid reservoir 11 and thus in surrounding tissue so that tissue death occurs in the desired way. Data on temperature from temperature sensors 23 and 37 can also be shown continuously on display unit 33.

Pumping and cooling device 34 is connected with cooling channels 27 and pumps suitable cooling fluid through cooling channels 27 in order

primarily to cool feed cable 15 while it is being extended forward to heating device 10. Fluid supply device 35 is used when fluid reservoir 11 is to be filled and expanded. The filling can be monitored by control unit 32.

A preferred embodiment according to the invention also includes a pressure meter 39, which is operatively connected with fluid supply device 35. Pressure meter 39 is also operatively connected with central control unit 32 in order that the pressure in fluid reservoir 11 can influence the process of treatment. The pressure can be changed depending on how the treatment is progressing. For reasons of safety the treatment should be able to be interrupted if the pressure in fluid reservoir 11 falls abruptly, for example, for the reason that fluid reservoir 11 breaks.

Reservoir 11 is completely closed and contains a certain volume of fluid 13 with suitable properties of heat transfer. Examples of such fluids are silicon oil and water. Reservoir 11 is embodied of elastic silicon or another material with corresponding elastic properties, for example, latex. Even treatment catheter 12 can be embodied of silicon or similar material, as can bladder 18.

The embodiment shown in FIG 6 includes feed cable 15 in form of a coaxial cable with shielding covering 40 and inner conductor 41. The covering also constitutes an outer conductor. At the end of covering 40 the inner conductor is then an antenna, which in this embodiment is a coil-wound antenna. Other embodiments of the antenna are also possible within the framework of the invention.

First heating device 10 and second heating device 29 are comprised of a combined means in the form of the coaxial cable that conducts microwaves to a radiator (antenna) and direct current or low-frequency alternating current to a resistor. The resistor and the radiator are comprised of the same physical construction, which functions differently dependent on whether it is fed with microwaves or direct current/low-frequency alternating current. In this variant the antenna itself is comprised of a closed loop with a certain inductance L and a resistance R that connects the inner conductor of

the coaxial cable with the outer conductor in such a way that the loop, when it is fed with microwave energy, functions as an antenna and radiates the energy. In the case when it is fed with direct current/low frequency alternating current it functions only as a resistive load and develops heat when the current passes through the loop. The antenna also displays a certain capacitance.

In a typical case the loop has a pure resistance in the range of 1-20 ohms, for example 1 ohm with direct current, while with high frequency (HF) it has 50 ohms as a result of inductance in the coil. The resistive load will be a lesser part of the total HF-load, so that the larger part of supplied microwave power radiates out from the antenna. The material in the coil is chosen so that suitable resistance is obtained (i.e., in the range of some ohms). When such an antenna is fed with 40 watt microwave power (a typical value with microwave treatment), in the above-mentioned case $1/50 \times 40 = 0.8$ watt heating power will be developed in the radiator itself, while 49 watts radiate out. This means that the antenna does not significantly affect the temperature of the fluid in reservoir 11 through direct effect, since 0.8 W is too little power to cause effective heating of reservoir 11.

Conversely, when the construction is used instead only with direct current/low frequency alternating current 25W of heat will be developed and directly heat the fluid in balloon 11 at an input current of 5 amperes (5 volts input). It is worth noting that the coaxial cable is a suitable carrier of both microwave energy and direct current/alternating current up to some tens of amperes. By using coaxial cable 15 in this dual manner, one gains the advantage of having a cable system that at the same time is tough enough to conduct both microwave energy and high current (10A) at a low voltage (for example 10 Volts). This means that one can avoid high voltage for the direct current component with its concurrent safety risk for the patient.

In an alternate embodiment according to FIG 7 first heating device 10 is physically separated from second heating device 29. The radiating element that constitutes first heating device 10 includes a low-resistive loop

(coil). The coil is connected in series with resistance arranged inside fluid reservoir 11, typically in the range of some few ohms, for example, 5 ohms. The resistance in a preferred embodiment is placed far forward closest to bladder neck 21' and the microwave radiator is located farther back and centrally in the prostate. With this embodiment it is possible to achieve effective heating of an arbitrary part of the prostatic urethra with its mucous membrane and of the tissue located near it through suitable positioning of fluid reservoir 11. This embodiment is especially suitable when the tissue surrounding the prostatic urethra closest to bladder neck 21' and bladder neck 21' itself are to be treated. At the same time central parts of prostate 19 can be treated in a conventional manner with microwave radiation from first heating device 10.

FIG 8 generally shows components that can be included in energy supply unit 14. A microwave generator 42 produces microwave energy at a suitable frequency and a DC assembly 43 produces direct current. Microwave generator 42 and DC assembly 43 are both connected with an electronic unit 44, which in an embodiment according to the invention alternately supplies direct current and microwave energy to heating device 10, 29. Electronic unit 44 can include a coaxial relay that alternatively transmits direct current/low frequency alternating current in feed cable 15 and alternating microwaves.

By alternately transmitting microwaves and direct current/low frequency alternating current through the construction, the operator has the possibility to moderate the temperature in fluid reservoir 11 with the resistive part of the invention in order to achieve coagulation of tissue in close proximity to the prostatic urethra including the bladder neck. The temperature in fluid reservoir 11 should not be less than 140 (60 °C) and best up towards 176 °F- 194 °F (80 °C- 90 °C) or more. This is in order to make brief treatment possible. During the microwave phase more peripherally lying areas are affected, but the temperature there will be lower, around 122 °F- 140 °F (50 °C- 60 °C). For this reason the time taken in order

to achieve coagulation of tissue in these more distant areas will be correspondingly longer. The microwave part is especially important for larger prostate glands because of its greater range in comparison with pure heat conduction. Typical radial penetration of coagulation by means of heat
 5 conduction from fluid reservoir 11 is 5-8 mm. Corresponding penetration of coagulation by microwaves is up to 20 –30 mm.

In a typical embodiment the system is run in multiplex intervals of 1-60 seconds with microwaves and 1-60 seconds with direct current / low frequency alternating current depending on which temperature obtains at the
 10 time in peripheral areas of the prostate or in the area near the prostatic urethra, after which the sequence is repeated. In an alternate embodiment the treatment is first completed with the fluid typically for 15 minutes without interruption, and after that using only microwaves for another 45 minutes.

In an alternate embodiment in accordance with the invention electronic
 15 unit 44 includes a so-called bias-tee component. This isolates microwave generator 42 from direct current assembly 43, so that these are simultaneously connected with feed cable 15. In this way microwave energy can be supplied at the same time as direct current or low frequency current. The different characteristics dependent on frequency in first heating device
 20 10 and second heating device 29 mean that microwave energy or direct current energy can be supplied and emitted simultaneously from the respective heating devices. A bias-tee component includes, as in indicated in FIG 8, essentially a condenser for isolation of microwave generator 42 from direct current assembly 43 and an inductance for isolation of direct current
 25 assembly 43 from microwave generator 42.

PATENT CLAIMS

What is claimed is:

1. A device for heat treatment of the prostate, comprising a treatment catheter with an expandable fluid reservoir and first heating means which is
5 located within said treatment catheter and emits electromagnetic radiation for heating of the surrounding prostatic tissue, said treatment catheter being provided with a free end which is insertable through urethra into the urinary bladder of a patient and a second end connected to an energy supply unit arranged outside of the patient's body, wherein

10 second heating means is provided in thermal contact with the liquid in the fluid reservoir for heating of the liquid in the fluid reservoir,

said fluid reservoir is positioned external to the treatment catheter so that in its operative position it engages with and fills urethra which extends
15 through prostate adjacent to the prostate neck 21', and

said first heating means and second heating means are operatively connected with the energy supply unit.

2. A device according to Claim 1, wherein said first heating means is
20 provided as an antenna element emitting microwaves and said second heating means comprises an electric lead resistance.

3. A device according to Claim 2, wherein said second heating means comprises a lead resistance separated from the antenna element and
25 provided axially displaced along the treatment catheter from said first heating means towards the free end of the treatment catheter.

4. A device according to Claim 1, wherein said first heating means is provided as a coil antenna and said second heating means comprises a lead
30 resistance in said coil antenna.

5. A device according to Claim 1, wherein said energy supply unit comprises a microwave generator for supply of microwave energy to said first heating means and a direct current or low frequency power source for supply of electric energy to said second heating means.

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6. A device according to Claim 5, wherein said first heating means is electrically connected to said second heating means and the microwave generator is operatively connected to said low frequency power source for jointly supplying microwave energy and electric energy to said first heating means and said second heating means.

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7. A device according to Claim 5, wherein a first temperature sensor (23, 23', 23'') is provided for measuring of temperature in the prostatic tissue and a second temperature sensor is provided for measuring of temperature in the fluid reservoir, and wherein a central control unit operatively connected to said energy supply unit is provided for controlling the supply of microwave energy to said first heating means as a function of the temperature in the prostatic tissue and for controlling the supply of electric energy to said second heating means as a function of the temperature in the fluid reservoir.

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8. A device according to Claim 1, wherein said energy supply unit is connected to said first heating means and to said second heating means via an electronic unit, and wherein said electronic unit is provided for simultaneous supply of energy to the two heating means (10; 29).

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9. A device according to Claim 1, wherein said energy supply unit is connected to said first heating means and to said second heating means via an electronic unit, and wherein said electronic unit is provided for non-simultaneous supply of energy to the two heating means (10; 29).

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10. A device according to Claim 2, wherein said lead resistance of the antenna element coupled in series with the lead resistance of said second

heating means is in the range of 1-20 ohms, and the microwave impedance for a microwave signal supplied from the energy supply unit is approximately 50 ohms due to the inductance and capacitance of the antenna element.

- 5 11. A device according to Claim 1, wherein a feed cable connects said energy supply unit to said first heating means and to said second heating means, and wherein said feed cable is provided as a coaxial cable with an inner conductor for supply of microwave energy and electric energy and with a covering acting as a return lead.

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12. A method for heat treatment of the prostate, comprising a treatment catheter equipped with an expandable fluid reservoir and first heating means which is located within said treatment catheter and emits electromagnetic radiation for heating of the prostatic urethra as well as the prostatic tissue surrounding the urethra, wherein said treatment catheter is provided with a free end which is inserted through urethra into the urinary bladder of a patient, and a second end is connected to an energy supply unit arranged outside of the patient's body, comprising the following steps:

operative connection of said first heating means to the energy supply unit,

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positioning of said fluid reservoir externally to the treatment catheter so that in its operative position it will expand and engage with urethra which extends through prostate adjacent to the prostate neck 21',

heating of liquid in the fluid reservoir through second heating means which is arranged to be in thermal contact with the liquid separately from said first heating means.

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13. A method according to Claim 12, comprising supply of microwave energy to said first heating means simultaneously with supply of electric energy to said second heating means.

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14. A method according to Claim 13, comprising

continual measuring of the temperature of the prostatic tissue and the liquid in the fluid reservoir, and

control of the supply of microwave energy as a function of the temperature of the prostatic tissue, and control of the supply of electric energy as a function of the temperature of the liquid in the fluid reservoir.

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15. A method according to Claim 12, comprising supply of microwave energy to said first heating means non-concurrently with supply of electric energy to said second heating means.

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16. A method according to Claim 12, comprising heating of deep-lying prostatic tissue through emitting of microwave energy from said first heating means and destruction of the prostatic urethra, its mucosa and the closest surrounding tissue as well as the bladder base primarily via direct heating through said second heating means.

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The invention relates to a method and a device for heat treatment of prostatic tissue. The device comprises a treatment catheter with an expandable fluid reservoir and first heating means which is arranged within the treatment catheter and emits electromagnetic radiation for heating of the surrounding prostatic tissue. A second heating means is provided in thermal contact with the liquid in the fluid reservoir for heating of the liquid in the fluid reservoir as well as the tissue located in the immediate surrounding of the reservoir.



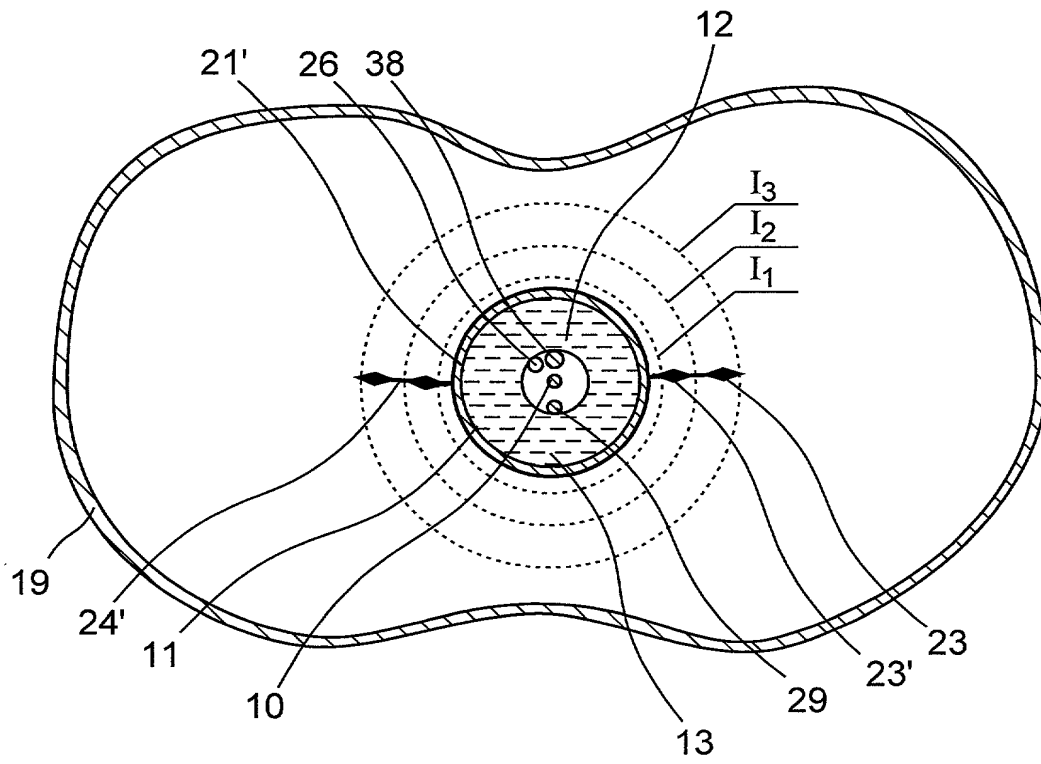


FIG 3

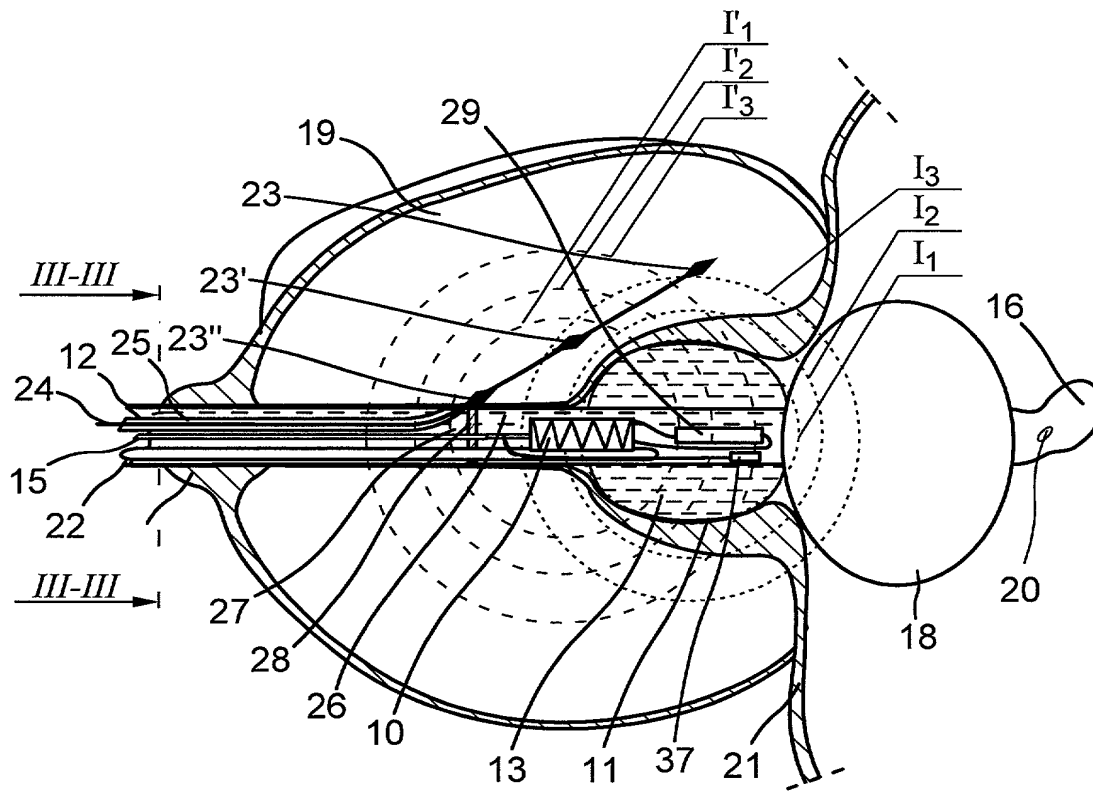


FIG 4

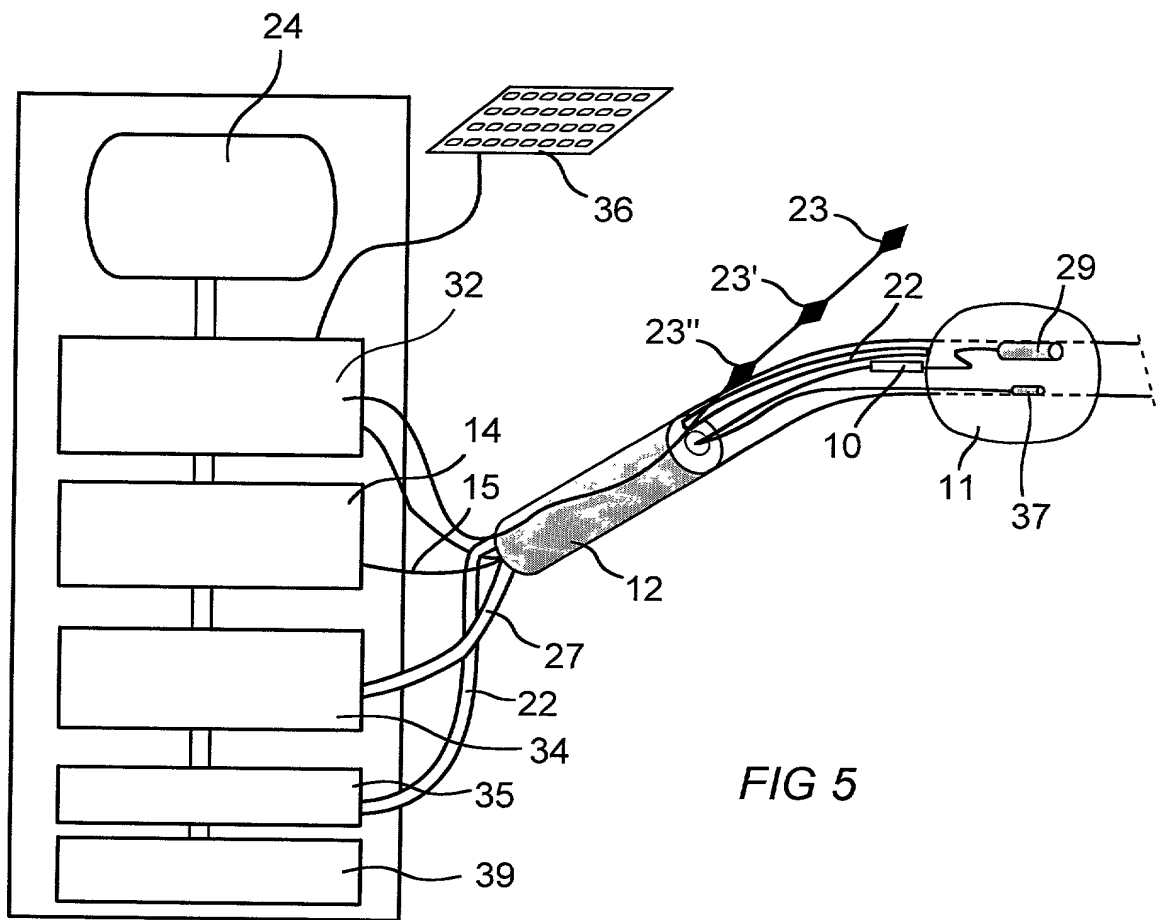


FIG 5

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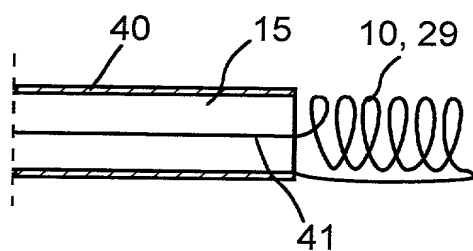


FIG 6

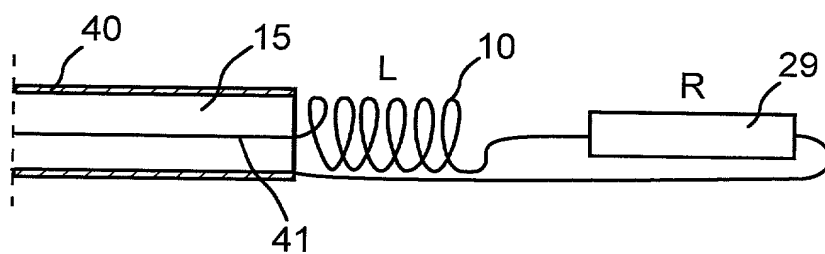


FIG 7

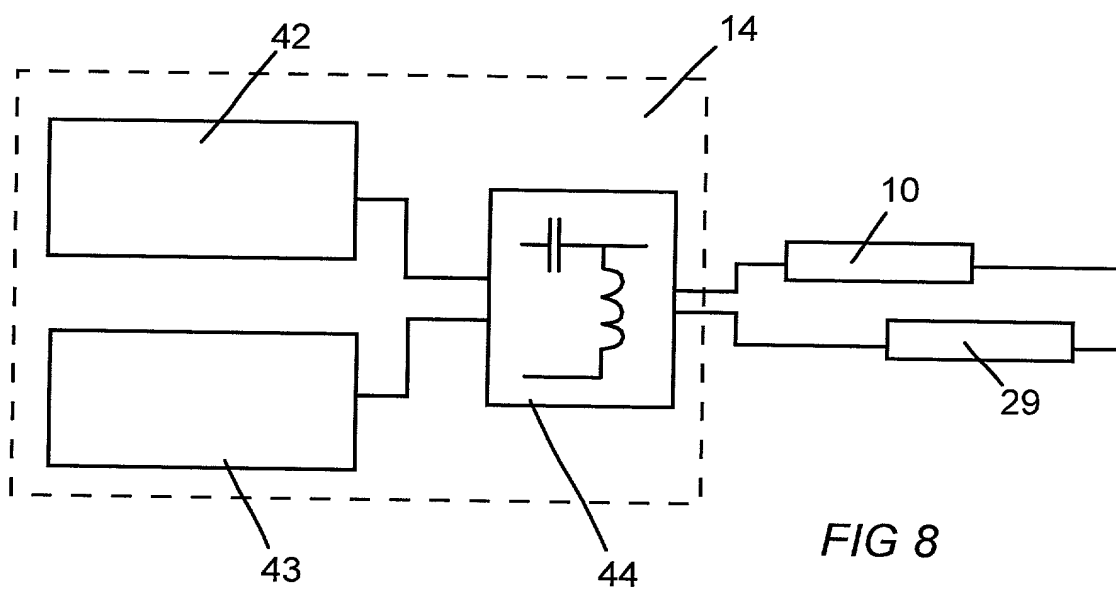


FIG 8

Docket No.
4298-137

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

METHOD AND DEVICE FOR COMBINED HEAT TREATMENT OF BODY TISSUE

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____ and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
SE 9900382-4	Sweden	04/02/99	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	
_____	_____	_____	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	
_____	_____	_____	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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